

Washing with emollients. An influence of ceramides or silicones on sensory differences, washing and moisturizing properties of a 3-in-1 emollient ointments

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Introduction

Emollients are medical moisturizers used to treat eczema and other dry skin symptoms. Emollients soothe and relieve itch, producing a protective layer on the skin surface. Some of emollient formulations may combine three functions like washing, bathing and moisturizing. Daily emollient bath/shower is recommended to remove dirt and skin debris, which could cause infection, irritation, itch. Plain water without emollient will dry out the skin, whereas an emollient will gently cleanse the skin, reduce itchiness and repair the skin barrier by trapping moisture. Objectives of this study was to evaluate safety and efficacy of two versions of emollient ointments based on canola oil, hempseed oil, shea butter and paraffin on washing and moisturizing properties. Differences between both versions was that one of them additionally comprised of ceramides (16916A) and the second one - of dry emollient - cyclopentasiloxane (16916).

Results – *in vitro* cytotoxicity

In vitro MTT study confirmed that 16916 and 16916A did not exhibit cytotoxic properties towards L929 cells at the concentration of at least or equal to 0,001% and 0,01%, respectively.

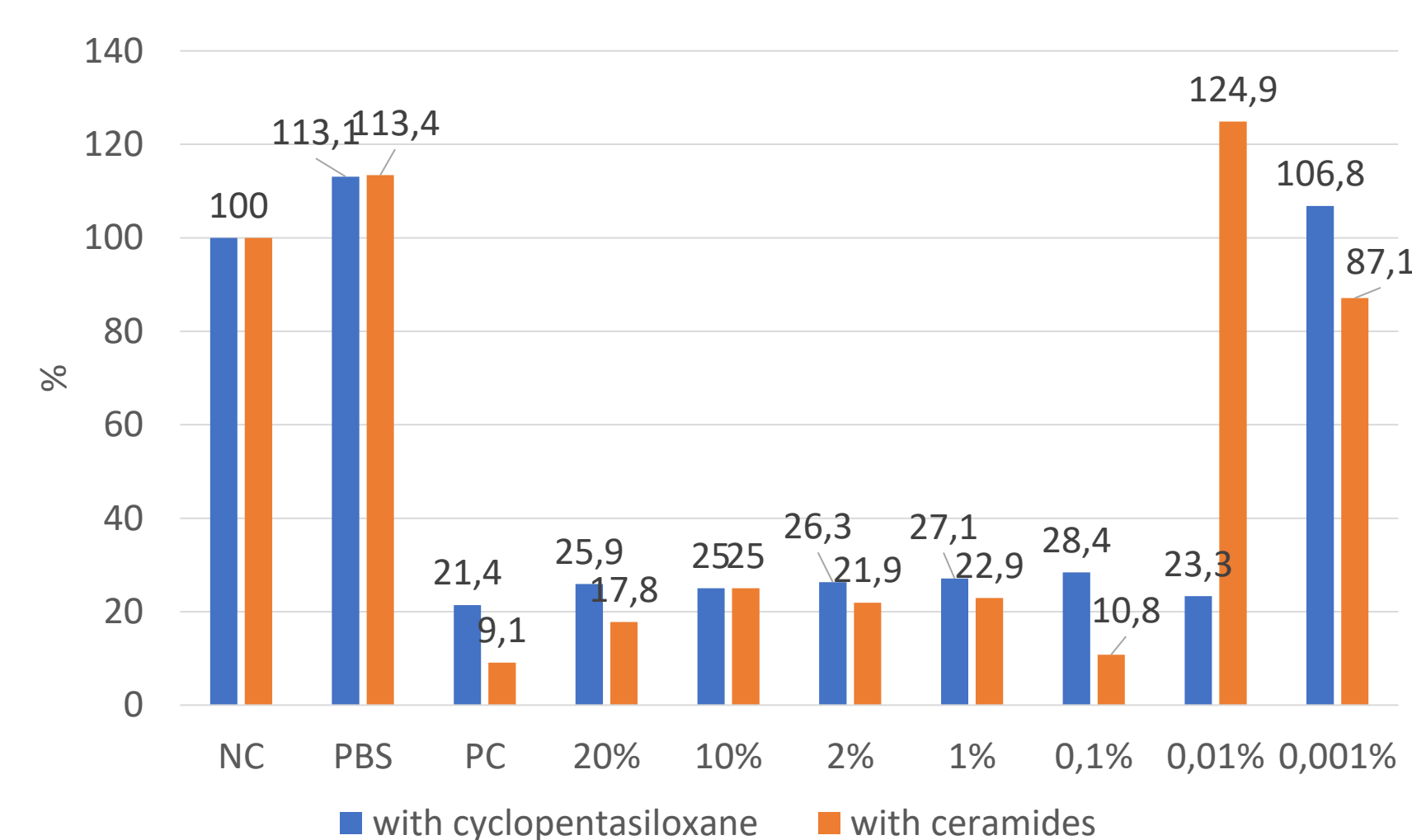


Figure 2. Cytotoxicity of ointments 16916 and 16916A on L929 cells. Viability <70% of the control – cytotoxic potential. PC – 0,5% SDS. **The tested product is non-cytotoxic** at the concentration of at least or equal to 0,01% for 16916A (cells viability: 124,9%) and 0,001% for 16916 (cells viability: 106,8%).

Materials and Methods

Safety of a products was evaluated in accordance with ISO 10993 by performing *in vitro* MTT cytotoxicity test whereas irritation potential was tested on Epiderm skin model. Medium was collected to perform Elisa for interleukin IL-18 (only for version with ceramides). Penetration through stratum corneum of the tested device was measured by Raman spectroscopy. For observational study, 8 children (age 1-16 yr.) and 14 adults (29-69 yr.) with dry skin and mild to moderate atopic dermatitis, were enrolled for the test. Participants and caregivers were instructed to use both ointments as bath-additives or as a soap-substitute or apply both products as moisturizers for 10 days, one or twice daily.

Results – *ex vivo* irritation potential

The products did not express irritation potential (EpiDerm tissue viability for product with cyclopentasiloxane was 69,4% and with ceramides 107,3%, respectively).

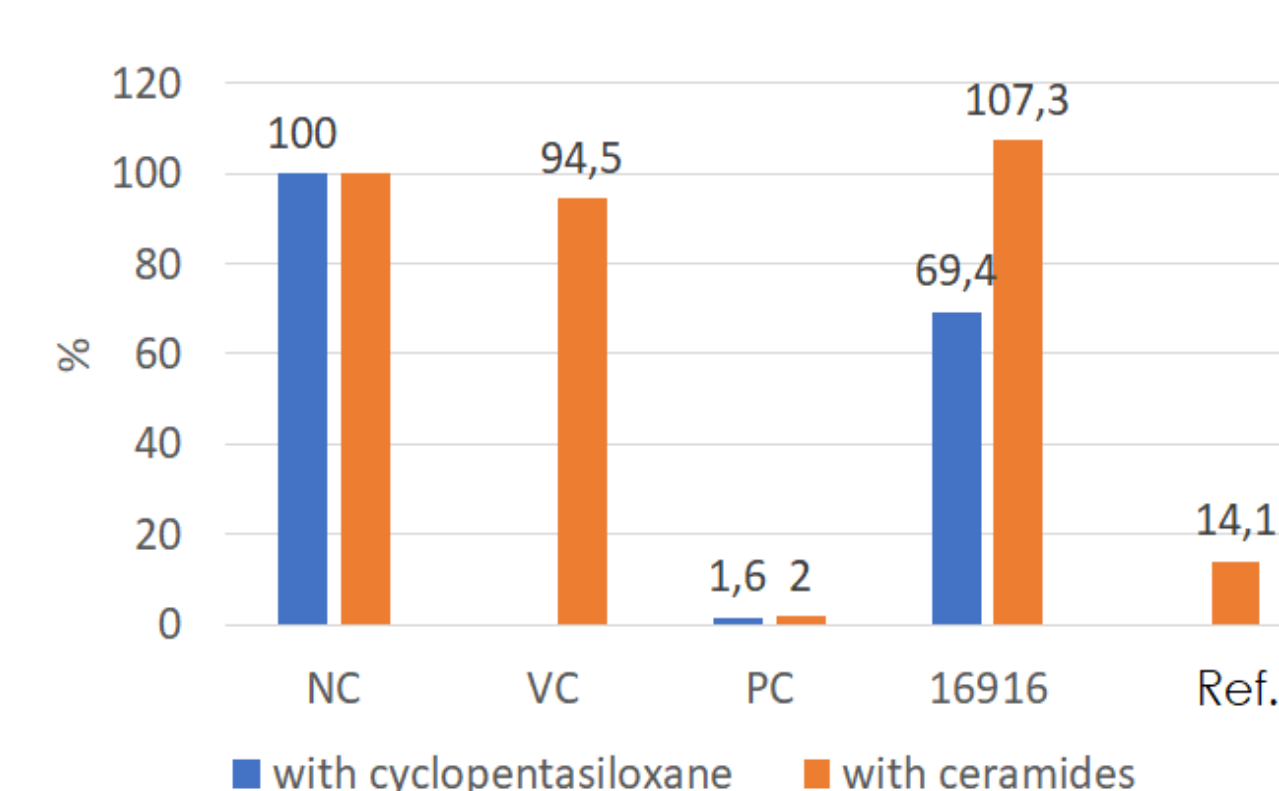


Figure 2. Skin irritation potential of ointments tested on EpiDerm model. PC – 1% SDS – irritant. VC – vehicle PBS. Tissue viability ≤ 50% of the control (PBS) – irritant. Tissue viability ≥ 50% of the control – non-irritant. Ref. - Phenoxyethanol - Methylparaben - Ethylparaben - Propylparaben - Butylparaben **The study products are non-irritating** (tissue viability – 69,4% and 107,3% respectively).

Results – observational test

Table 1. Application properties of both ointments with regards to their way of usage.

Application properties as bath emulsion	% of respondents	
	16916 with cyclopentasiloxane	16916A with ceramides
Ointment is dissolving in hot water easily	43%	67%
It enables to prepare milky emulsion in bath tub	57%	92%
It creates delicate emulsion in water	86%	92%
Application properties as cleanser for shower wash		
% of respondents		
Spreads easily	100%	94%
Rinses-off easily from the skin	100%	94%
Application as leave on moisturizer		
% of respondents		
It creates protective layer on the skin	88%	100%
Leaves sticky skin	100%	50%

Volunteers assessed that the product version with ceramides displays better properties in preparing bath. Also, skin condition was better assessed for the version with ceramides. As a skin “leave-on” moisturizer, skin condition was slightly better evaluated in version with silicones, however overall assessment of application properties and efficacy was higher for emollient with ceramides. Product version with cyclopentasiloxane during test caused some mild side effects (in 3 volunteers).

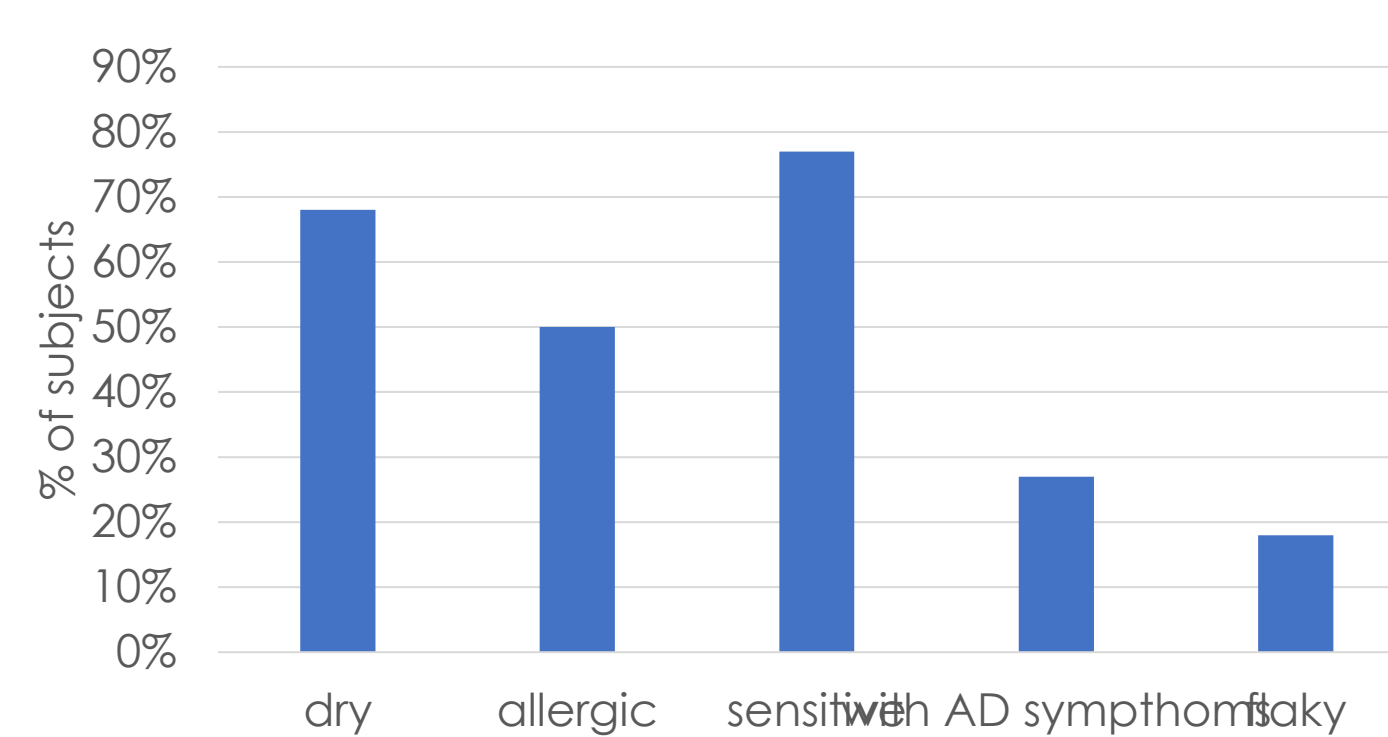


Figure 1. Skin type of volunteers taking part in the observational study of the ointments.

Table 2. Subjective evaluation from observational study

Subjective evaluation of ointments in different ways of usage	% of respondents					
	Bath emulsion		Cleanser for shower wash		Leave-on moisturizer	
	16916	16916A	16916	16916A	16916	16916A
Moisturized	86%	83%	77%	84%	88%	94%
Nourished	100%	100%	69%	88%	94%	78%
Soothed	71%	83%	77%	81%	88%	83%

Results – sensitisation properties *in vitro*

Elisa did not show any significant changes in the concentration of IL-18 indicating lack of sensitisation properties of the product with ceramides (16916A).

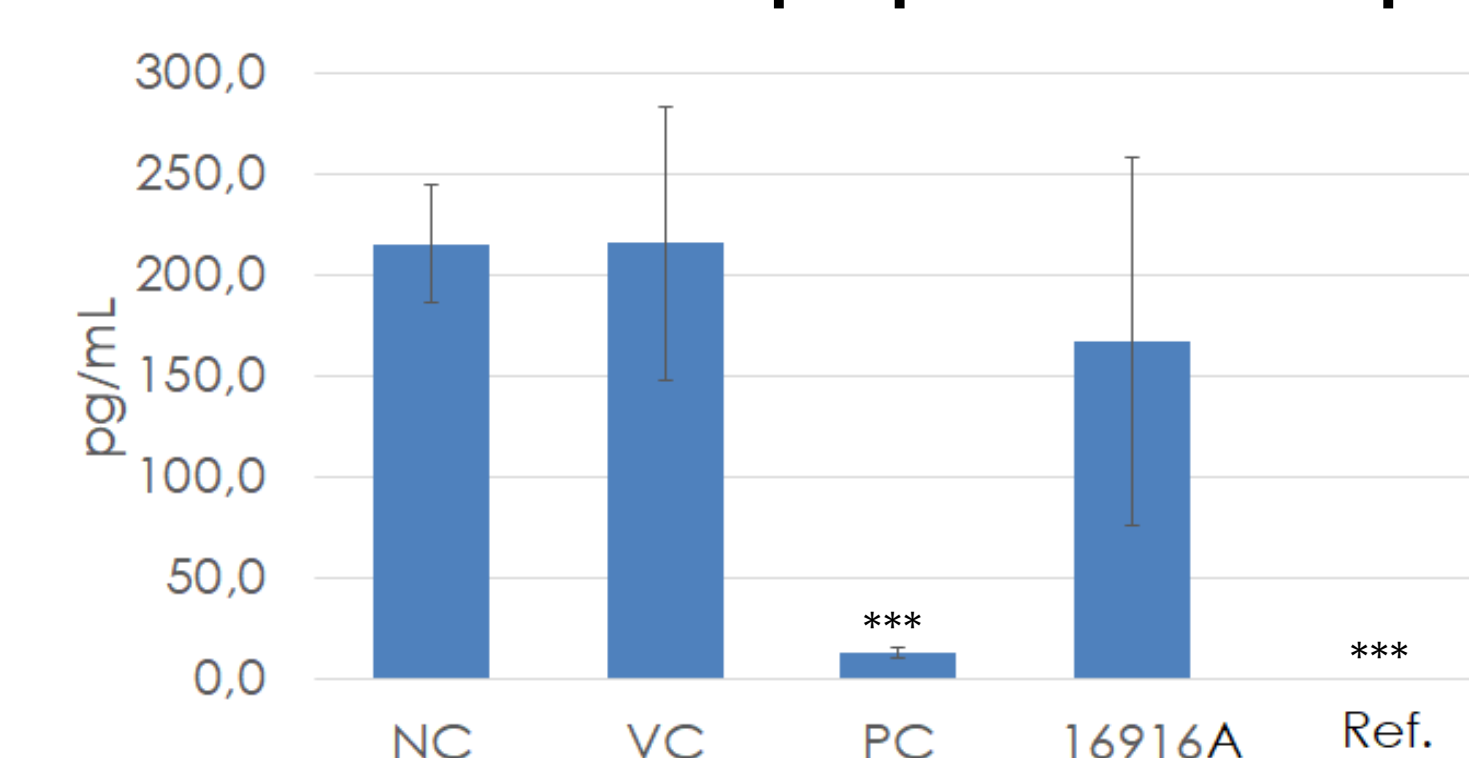


Figure 3. Skin sensitisation potential of ointments tested on EpiDerm model. PC – 1% SDS – irritant/non-sensitizer. Ref. - Phenoxyethanol - Methylparaben - Ethylparaben - Propylparaben - Butylparaben – irritant/sensitizer. **The study product do not cause sensitisation properties.** Differences between NC and tested substance were statistically significant at: *** - p<0.001

Results – penetration through sc

Raman spectroscopy revealed that both formulations did not penetrate to deeper layers of skin tissue, but only created protective layer on the skin.

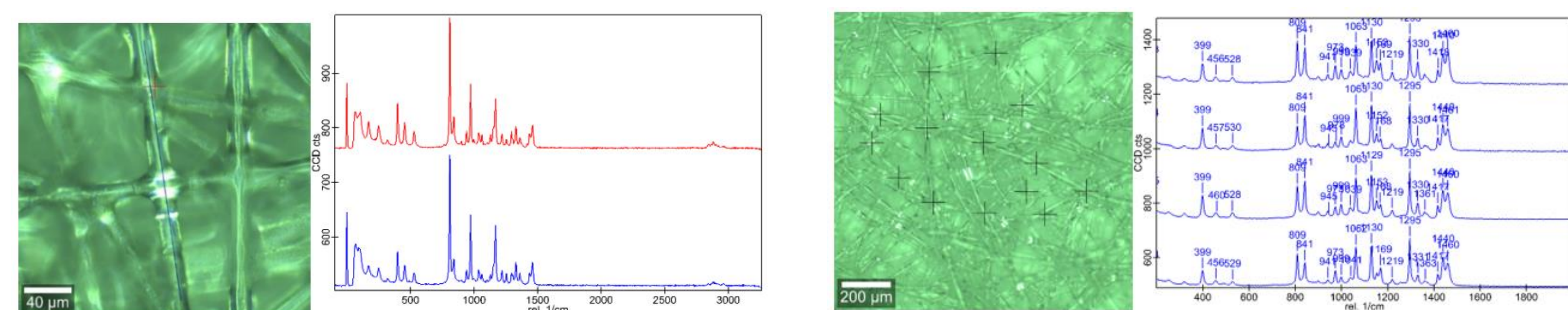


Figure 4. Both figures represent surface of artificial membrane Strat-M SurF after 4 hours of application of both ointments (on the left – 16916, on the right – 16916A) on SurF layer. After comparable analysis of spectra of ointments and SurF, we did not detect spectra for ointments. **It suggests that both emollient products did not penetrate through sc, but only creates protective layer on the skin surface.**

Results – overall assessment

Table 3. Overall assessment. Satisfaction from products usage was comparable for both ointment types and willingness to use it the future was higher for ointment no. 16916A with ceramides.

Satisfaction from product usage	% of subjects		Willingness to use product in the future	% of subjects	
	16916	16916A		16916	16916A
As bath emulsion	86%	85%	As bath emulsion	57%	92%
As cleanser for shower wash	87%	83%	As cleanser for shower wash	57%	81%
As moisturizer	86%	81%	As moisturizer	78%	83%

Conclusions

Better sensory parameters and no adverse effects during the test indicate that the emollient with ceramides represent a promising, cost-effective (three ways of usage), 3-in-1 approach in atopic dermatitis treatment.